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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/069,703 04/29/98 TAPOLSKY

G VIRO:034

EXAMINER

HM22/0717

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ART UNIT

PAPER NUMBER

1617

DATE MAILED:

07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/069703

Applicant(s)

TAPOLSKY

Examiner

WEBMAN

Group Art Unit

167

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/11/01
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-18, 33 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1-18, 33 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 15
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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The election of species requirements are withdrawn.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1, 3-6, 9, 11, 15, 17, 18, 18, 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Kamiya et al.

Kamiya et al teach a patch comprised of two water soluble layers (abstract). Antiseptics are specified (column 8 line 13). Gelatin and polyacrylic acid are specified in one layer and polyvinyl alcohol in the second layer (Table I). Propylene glycol is specified (column 5, line 11). Water is disclosed (column 4 lines 60-67).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-15, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Inaba et al (U.S. patent 4,552,751 equivalent to EPA 0050480).

Inaba et al teach a three layer composition comprising an outer control release layer comprising polyvinyl pyrrolidone. And hydroxy alkyl cellulose (Figure 1 and claim 1A). A drug

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storing layer comprising hydroxypropyl cellulose^{is disclosed} (claims 8). Glycerin is specified (claim 1C).

Prostaglandins, known for lowering blood pressure, are disclosed (column 1 line 48).

¹
Vinyl acetate is specified (claim B). As to the claimed adhesive layer, this property must be inherent in the Inaba et al composition because it possesses the same polymer as that claimed as an adhesive, namely, polyvinyl pyrrolid^{one}.

The disclosure is objected to because of the following informalities: On page 7 line 28, page 16, lines 23, 27, page 17 lines 4, 9, 12, 14, 16, 21 and page 19 line 3 "ETC" is nonlimiting. "And the like" is suggested.

Appropriate correction is required.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a film containing a drug, does not reasonably provide enablement for a film not containing a drug. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Page 6 lines 6-28 specify a film containing a drug.

Thus, "optionally" in claim 1 impermissibly broadens the scope of the claim.

Claims 3, 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 17 lines 6, 7 "said first erodible" Has no antecedent in the preamble. In line 2 is "A" intended before pharmaceutical?"

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In claim 3 lines 2, 7 "selected form" is indefinite. Is "the group consisting of" intended after the phrase? If so, "or" in lines 6, 8 is indefinite. A Markush group with "selected from" language should be a list of elements, the last preceded by "and".

In lines 5, 6 "Derivatives" is Vague; which ones?

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) -308-4432. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Moezie, can be reached on (703) -308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) -305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) -308-1235.

Webman/LR

June 21, 2001


EDWARD J. WEBMAN
PATENT EXAMINER
GROUP 1500